UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON DIVISION

RICHARD O'NEILL, on behalf of himself and all others similarly situated, Plaintiff, **v.** **SOLCO HEALTHCARE U.S., LLC,** and, **PRINSTON PHARMACEUTICAL, INC.,** Defendants.	**Civil Action No.:** **Jury Trial Demanded** **Complaint-Class Action**

CLASS ACTION COMPLAINT

Plaintiff Richard O'Neill, on behalf of himself and all others similarly situated, brings this action against Defendants Solco Healthcare U.S., LLC ("Solco") and Prinston Pharmaceutical, Inc. ("Prinston") (collectively "Defendants"). Plaintiff alleges, with personal knowledge as to his own actions, and on information and belief and the investigation of his counsel as to the actions of others, as follows:

NATURE OF THE CASE

1. This is a class action lawsuit regarding Defendants' manufacturing and distribution of Valsartan generic prescription medications contaminated with N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity ("Valsartan" or "NDMA-containing medication"). In turn, Defendants sold this contaminated generic medication to Plaintiff and other similarly situated consumers.
2. Originally marketed under the brand name Diovan, Valsartan is a prescription medication mainly used for the treatment of high blood pressure and congestive heart failure. However,

due to manufacturing defects originating from overseas laboratories in China, certain generic formulations have become contaminated with NDMA.

3. NDMA is a semivolatile organic chemical. According to the U.S. Environmental Protection Agency, NDMA "is a member of N-ni-trosamines, a family of potent carcinogens." While NDMA is not currently produced in the United States other than for research purposes, it was formerly used "in production of liquid rocket fuel," among other uses. NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. Exposure to NDMA, such as through the contaminated Valsartan medications, can cause liver damage and cancer in humans. NDMA is classified as a probable human carcinogen, and animal studies have shown that "exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels."

4. On July 13, 2018, the U.S. Food & Drug Administration ("FDA") announced a voluntary recall of several brands of Valsartan, including those manufactured and distributed by Defendants Solco and Prinston. The recall was due to the presence of NDMA in the recalled products. The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured." The FDA is "investigating the levels of NDMA in the recalled products, assessing the possible effect on patients who have been taking them and [determining] what measures can be taken to reduce or eliminate the impurity from future batches produced by the company."

5. Generic drugs reach the market when the brand-name version of the drug comes off patent, and other competitors are able to seek approval for, market, and sell bioequivalent versions

of the brand-name drug. These generic equivalents are supposed to be of equal quality and equal safety. Defendant Solco, who is in the business of marketing and distributing generic pharmaceuticals, explains on its website:

> Generic pharmaceuticals are **identical (bioequivalent)** to the branded medications with regard to:
>
> • Intended use
> • Effectiveness
> • Dosage form
> • Strength
> • **Safety**
> • Route of administration
> • **Quality**
>
> Defendant Solco's website further explains:
>
> Our products are **manufactured in state-of-the-art GMP facilities in China using the highest quality assurance standards that meet the FDA regulatory requirements**. Solco is a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical, leaders in drug development and manufacturing of active pharmaceutical ingredients (API) and finished dosage products. Together we strive to offer greater access to affordable medications that **you can trust**.

6. However, each of these representations and warranties made by Solco are false. To the contrary, Solco's NDMA-containing medications are neither safe nor of "high quality." In fact, the European Medicines Agency explained that "NDMA is an unexpected impurity that was not detected by routine tests carried out by [Solco and Prinston's parent company in China,] Zhejiang Huahai," and that the change in the manufacturing process which led to the impurity was introduced in 2012 and is "believed to have produced NDMA as a side product." As such, this contamination has likely existed for approximately six years without being detected.

7. At all times during the period alleged herein, Defendants represented and warranted to consumers that their generic Valsartan products were therapeutically equivalent to and

otherwise the same as brand DIOVAN®, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

8. However, for years, Defendants willfully ignored warnings signs regarding the operating standards at the Zhejiang Huahai Pharmaceuticals ("ZHP") manufacturing plant in China, and continued to allow ZHP to manufacture their Valsartan products for sale to consumers in the United States even after Defendants knew or should have known that their Valsartan products manufactured by ZHP contained or likely contained NDMA and/or other impurities.

9. These adulterated Valsartan drugs were introduced into the American market at least as far back as 2015 for Defendants to profit from their sale to American consumers, such as Plaintiff and Class Members. However, evidence now suggests that the contamination dates back at least as far as 2012. Plaintiff and Class Members paid for all or part of their Valsartan prescriptions that were illegally introduced into the market by Defendants and which were not fit for their ordinary use. Defendants have been unjustly enriched through the sale of these adulterated drugs since at least 2012. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state law.

10. Plaintiff and the Class were injured to the extent of the full purchase price of their NDMA-containing medications. These medications are worthless, as they are contaminated with carcinogenic and harmful NDMA, and are not fit for human consumption. Indeed, Plaintiff and the Class have been instructed to immediately stop using the medication, and have turned in their remaining medication for another, non-contaminated brand. Plaintiff and the Class are further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDMA, and for damages related to Defendants' conduct.

11. Plaintiff brings this action on behalf of the Class to recover damages and restitution for: (i) breach of express warranty pursuant to N.J.S.A. § 12A:2-313, (ii) breach of the implied warranty of merchantability pursuant to N.J.S.A. § 12A:2-314, (iii) violation of New Jersey's Consumer Fraud Act, N.J.S.A. §§ 56:8-1 et seq., and, in the alternative, (iv) violation of each state's consumer protection law.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below (the "Class"), is a citizen of a different state than the states in which the Defendants are citizens, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs.

13. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts in New Jersey, and otherwise conduct business within New Jersey through their business activities.

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this Judicial District, Plaintiffs reside in this Judicial District, and because Defendants (a) have conducted business in this Judicial District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution, and sale of contaminated Valsartan medications in this District; (b) conduct substantial business in this District; and (c) are subject to personal jurisdiction in this District.

PARTIES

15. Plaintiff Richard O'Neill is a citizen of the State of Kansas, who resides in Johnson County, Kansas. During all relevant time periods, O'Neill was prescribed, purchased and consumed NDMA-containing medication. O'Neill purchased the Valsartan medication from a pharmacy located in Johnson County, Kansas.

16. Defendant Solco Healthcare U.S., LLC ("Solco") is a limited liability company organized under the laws of the State of Delaware and maintains its principal place of business at 2002 Eastpark Boulevard, Suite A, Cranbury, New Jersey 08512. Defendant Solco conducts substantial business in the State of New Jersey. Defendant Solco boasts on its website that it "is an industry leader in marketing and distributing generic pharmaceuticals," and that it "currently markets 38 products," which "are manufactured in state-of-the-art GMP facilities in China using the highest quality assurance standards that meet the FDA regulatory requirements." Defendant Solco's website further states that it is "a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical, leaders in drug development and manufacturing of active pharmaceutical ingredients (API) and finished dosage products …. Together we strive to offer greater access to affordable medications that you can trust."

17. Defendant Prinston Pharmaceutical, Inc. ("Prinston") is a corporation incorporated under the laws of the State of Delaware, and maintains its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512. Defendant Prinston conducts substantial business in the State of New Jersey. Defendant Prinston explains on its website that "[Defendant] Solco Healthcare U.S. is the U.S. sales and marketing division of Prinston Pharmaceutical Inc."

GENERAL ALLEGATIONS

A. Valsartan Background

18. Valsartan is a potent, orally active nonpeptide tetrazole derivative which cases a reduction in blood pressure, and is used in the treatment of hypertension, heart failure, and post-myocardial infarction.

19. Valsartan is the generic version of the registered listed drug ("RLD") DIOVAN® ("Diovan"), which was marked in tablet form by Novartis AG ("Novartis") beginning in July 2001upon approval by the U.S. Food and Drug Administration ("FDA").

20. Diovan was an immensely popular drug. Globally, Diovan generated $5.6 billion in sales in 2011 according to Novartis's Form 20-F for that year, of which $2.33 billion was from the United States.

21. Diovan's FDA-approved label specifies its active and inactive ingredients. NDMA is not an FDA-approved ingredient of Diovan. Nor is NDMA an FDA-approved ingredient of any generic Valsartan product.

22. Although Novartis's Diovan patents expired in September 2012, Novartis was spared generic competition until approximately June 2014 because Ranbaxy Pharmaceuticals (the generic exclusivity holder) was unable to achieve FDA approval for its generic Diovan, thus effectively preventing other generic competition under the Hatch-Waxman Act, until Ranbaxy achieved FDA approval and began to market its generic product.

B. The Generic Drug Approval Framework

23. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

24. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

25. By contrast, generic drug companies submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

26. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is accepted as evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

27. In other words, generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

28. And finally, a generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

29. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug. Pharmacists, physicians, and patients can fully expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each and every prescription of it generic products.

30. According to the FDA, there are fifteen Abbreviated New Drug Applications ("ANDAs") approved for generic Diovan, i.e., Valsartan.

C. Background on Current Good Manufacturing Practices ("cGMPs")

31. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to assure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

32. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

33. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs' safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. § 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or delivered for introduction into interstate commerce. *See id.* § 331(a). States have enacting laws adopting or mirroring these federal standards.

34. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." U.S.C. § 351(j). Accordingly, it is a cGMPs violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

35. Indeed FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> (a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.
>
> 21 C.F.R. § 211.22(a).

D. <u>The Zhejian Huahai Pharmaceuticals("ZHP") Manufacturing Facilities</u>

36. Zhejiang Huahai Pharmaceuticals ("ZHP") is a subsidiary of Huahai Pharmaceutical, which is also the corporate parent of Defendants Prinston, Huahai US, and Solco. ZHP has Active Pharmaceutical Ingredient ("API") manufacturing facilities is located in Linhai City, Zhejiang Province, China. According to ZHP's website, ZHP was one of the first Chinese companies approved to sell generic drugs in the United States, and it remains one of China's largest exporters of pharmaceuticals to the United States and European Union.

37. ZHP serves as a contract manufacturer of Defendants' Valsartan products (including Defendant Teva's Valsartan products), and Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

38. ZHP has a history of deviations from FDA's cGMP standards that began almost as soon as ZHP was approved to export pharmaceuticals to the United States.

39. On or about March 27-30, 2007, the FDA inspected ZHP's Linhai City facilities. That inspection revealed "deviations from current good manufacturing processes (CGMP)" at the facility. Those deviations supposedly were later corrected by ZHP. The results of the inspection and the steps purportedly taken subsequent to it were not made fully available to the public.

40. On May 15-19, 2017, FDA again inspected ZHP's Linhai City facilities. That inspection resulted the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016 per the FDA's letter at the time. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated[.]" These findings were not made fully available to the public.

41. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample result. In fact, in one documented instance, the OOS result was attributed to "pollution" in the environment surrounding the facility. These are disturbing signs of systematic data manipulation designed to intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA.

42. The May 2017 inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and black metallic particles found in API batches.

E. Defendants Were Aware of Potential NDMA Contamination As Early As 2012

43. Upon information and belief, ZHP changed its Valsartan manufacturing processes in or about 2012, if not earlier.

44. According to the European Medicines Agency ("EMA") – which has similar jurisdiction to that of the FDA – "NDMA was an unexpected impurity believed to have formed as a side product after Zhejiang Huahai introduced changes to its manufacturing process in 2012."

45. NDMA is yellow, oily liquid with a faint, characteristic odor and a sweet taste, and is often produced as a by-product of industrial manufacturing processes.

46. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six (66) agents that are "probably carcinogenic to humans" (Classification 2A).

47. The U.S. Environmental Protection Agency has likewise classified NDMA as a probable human carcinogen by giving it a "B2" rating, meaning that it is "probably carcinogenic to humans" with little or no human data.

48. Anecdotally, NDMA has also been used in intentional poisonings.

49. NDMA is not an FDA-approved ingredient for branded Diovan or generic Valsartan. None of Defendants' Valsartan products identifies NDMA as an ingredient on the products' labels or elsewhere.

50. If Defendants had not routinely disregarded the FDA's cGMPs and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have found the NDMA contamination almost immediately.

51. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.
>
> 21 C.F.R. § 211.110(c).

52. And as reproduced above, Defendants' own quality control unit are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by ZHP.

53. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants and ZHP, the NDMA contamination in Defendants' Valsartan products would have been discovered in 2012. Defendants were thus on (at minimum) constructive notice that their Valsartan products were adulterated as early as 2012.

54. As alleged above, FDA investigators visited ZHP's facilities in May 2017. In the words of FDA inspectors, ZHP "invalidat[ed] [OOS] results [without] scientific justification" and did not implement "appropriate controls … to ensure the integrity of analytical testing" and routinely disregarded sampling anomalies suggestive of impurities.

55. These discoveries by the FDA's investigators suggest that ZHP and Defendants were specifically aware of impurities in the drugs being manufactured by ZHP, including specifically contamination of Defendants' Valsartan with NDMA. The efforts to manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce adulterated Valsartan into the U.S. market.

56. Defendants were also specifically aware of the manufacturing issues at ZHP based on Defendants' awareness of cGMP violations as early as 2012 based on their own monitoring of ZHP and of the Valsartan products being manufactured at ZHP, and based on the FDA's inspections of ZHP's facilities in March 2007 and May 2017.

57. Indeed, Defendant Solco and ZHP (as well as Huahai US) are owned by the same corporate parent, Huahai Pharmaceutical, and Solco was specifically aware should be imputed with actual knowledge of ZHP's willful deviations from cGMPs. Solco and Huahai US have offices in the same office building in Cranbury, New Jersey.

58. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated Valsartan into the U.S. market that was contaminated with NDMA. Defendants failed to recall their generic Valsartan products because they feared permanently ceding market share to competitors. And, upon information and belief, Defendants issued the "voluntary" recall of their Valsartan products only after the FDA had threatened an involuntary recall.

F. <u>FDA Announces Voluntary Recall of Defendants' Adulterated Valsartan</u>

59. On or about July 13, 2018, the FDA announced voluntary recalls by Defendants and other manufacturers for their Valsartan products manufactured by ZHP. The recall is for products distributed as early as October 2015. However, as alleged above, it is likely that Defendants' Valsartan manufactured 2012 and beyond was also contaminated with NDMA.

60. On or about July 27, 2018, the FDA announced expanded recalls of additional Valsartan products manufactured by Defendants and non-parties, and re-packaged by third parties.

61. As stated in the FDA's July 13, 2018 statement:

> The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.

G. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic Valsartan Products

62. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated Valsartan products.

63. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book. The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their Valsartan ANDAs. In securing FDA approval to market generic Valsartan in the United States as an Orange Book-listed therapeutic equivalent to Diovan,

Defendants were required to demonstrate that their generic Valsartan products were bioequivalent to brand Diovan.

64. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

65. By introducing their respective Valsartan products into the United States market under the name "Valsartan" as a therapeutic equivalent to Diovan and with the FDA-approved label that is the same as that of Diovan, Defendants represent and warrant to end users that their products are in fact the same as and are therapeutically interchangeable with Diovan.

66. Furthermore, Defendant Solco states on its "About Solco" page of its website that "[b]y using the same active ingredients, [Solco] produce[s] products which are identical (equivalent) to the branded medication."

67. On the "Drug Safety" page of Solco's website, Solco states that "Solco Healthcare is committed in providing … its patients with high quality, FDA-approved generic medications."

68. Defendant Solco lists its Valsartan products on its website with the statement that the "Reference Listed Drug" is "Diovan®" along with a link to download Solco's Valsartan Prescribing Information. Clicking the "Prescribing Information" link loads a .pdf of the Prescribing Information with a Solco URL address (http://www.solcohealthcare.com/uploads/product/info/valsartan-pi-artwork_170524_141555.pdf).

69. Each Defendant's Valsartan product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved Valsartan label, Defendants, as generic

manufacturers of Valsartan, made representations and express or implied warranties to consumers of the "sameness" of their products to Diovan, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated.

70. In addition, on information and belief, each Defendant affirmatively misrepresented and warranted to consumers through their websites, brochures, and other marketing or informational materials that their Valsartan product complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

71. The presence of NDMA in Defendants' Valsartan: (1) renders Defendants' Valsartan products non-bioequivalent (*i.e.*, not the same) to Diovan and thus non-therapeutically interchangeable with Diovan, thus breaching Defendants' express warranties of sameness; (2) was the result gross deviations from cGMPs thus rendering Defendants' Valsartan products non-therapeutically equivalent to Diovan, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' Valsartan containing an ingredient that is not also contained in Diovan, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, and/or negligently failed to ensure their Valsartan products' labels and other advertising or marketing statements accurately conveyed information about their products.

72. At all relevant times, Defendants have also impliedly warranted that their Valsartan products are fit for their ordinary purposes. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in

Valsartan. The presence of NDMA in Defendants' Valsartan means that Defendants have violated implied warranties to Plaintiff and Class Members. The presence of NDMA in Defendants' Valsartan results in Defendants' Valsartan products being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of Diovan), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes. were merchantable and/or fit for their ordinary purposes.

73. For these and other reasons, Defendants' Valsartan is therefore adulterated it was illegal for Defendants' to have introduced such Valsartan in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

74. Adulterated Valsartan is essentially worthless. No consumer would purchase an adulterated Valsartan product or is even allowed to purchase adulterated Valsartan product because it was illegally introduced into the United States. This is especially so given that alternative, non-adulterated Valsartan products or competing medications with the same approved indications were available from other manufacturers.

H. New Revelations Continue to Unfold About Other Manufacturing Plants

75. The recall of Defendants' Valsartan products is only the tip of the iceberg. Just two weeks after the FDA's initial recall announcement, the FDA issued another announcement expanding the recall to other Valsartan product manufactured at another plant in India, and by other non-parties. *See supra* n.4. On August 20, 2018 the FDA announced that it was going to test all Valsartan products for NDMA. Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known.

I. Fraudulent Concealment and Tolling

76. Plaintiff's and the Class Members' causes of action accrued on the date the FDA announced the recall of Defendants' generic Valsartan products.

77. Alternatively, any statute of limitation period is equitably tolled based on the Defendants' fraudulent concealment of material facts. Defendants each affirmatively concealed from Plaintiff and other Class Members their wrongful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of ZHP's cGMP violations with respect to Valsartan, and of the fact that their Valsartan products were adulterated and contaminated with NMDA, and were not the same as brand Diovan.

78. For instance, no Defendant revealed to the public that their Valsartan product contained NDMA or was otherwise adulterated or non-therapeutically equivalent to Diovan until the FDA's recall announcement in July 2018. The inspection report which preceded the recall announcement was heavily redacted (including the names of the drugs affected by ZHP's cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

79. Each Defendant continued to represent and warrant that their generic Valsartan products were the same as and therapeutically interchangeable with Diovan.

80. For instance, Huahai US publicly announced on its website that, contrary to the FDA's pronouncements, that no impurity was discovered until June 2018.

81. Because of this, Plaintiff and other Class Members did not discover, nor could they discover through exercise of reasonable diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiff and Class Members into believing that the prices paid for

Valsartan were appropriate for what they believed to be non-adulterated drugs despite their exercise of reasonable and ordinary diligence.

82. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff was unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

J. Extraterritorial Application of New Jersey Law as to Defendants

83. As alleged above, the Defendants Solco and Prinston Pharmaceuticals named herein maintain their corporate headquarters in New Jersey.

84. The express and implied warranties alleged herein were made from and originated from Defendants' respective headquarters in New Jersey.

85. The misrepresentations and/or material omissions regarding the therapeutic equivalence of the Defendants' Valsartan products to brand Diovan, and regarding the Defendants' cGMP violations and/or distribution of adulterated Valsartan in the United States were made from the Defendants' New Jersey.

86. Plaintiff intends to seek additional discovery to show that Defendants' warranties and breach thereof, and violations of consumer protection statutes occurred and emanated primarily from New Jersey in the case of the Defendants.

SUBSTANTIVE ALLEGATIONS

87. On or about May 4, 2017, O'Neill was prescribed and purchased Valsartan.

88. Since on or about May 4, 2017, O'Neill consumed the Valsartan medication as directed.

89. On or about July 7, 2018, O'Neill last purchased Valsartan medication.

90. On or about July 23, 2018, O'Neill received a letter dated July 20, 2018, informing him of the Valsartan medication's recall.

91. O'Neill immediately contacted his pharmacy and doctor to obtain a non-contaminated prescription.

92. On or about July 26, 2018, O'Neill was prescribed and purchased a new non-contaminated prescription.

93. O'Neill relied on the express and implied warranties of Defendants that the Valsartan products he purchased and consumed were safe for human consumption.

94. Among other manufacturers, O'Neill received NDMA-containing medications from Defendants Solco and Prinston.

95. O'Neill's Valsartan medication was contaminated with NDMA.

96. As a direct and proximate result of being prescribed and consuming NDMA-containing medication, as well as relying on express and implied warranties, O'Neill sustained actual damages, in an amount including but not limited to the full purchase price of the NDMA-containing medication.

CLASS ACTION ALLEGATIONS

97. O'Neill brings this action on his own behalf and additionally, pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3), on behalf of a nationwide class of all persons in the United States who have purchased NDMA-containing medication (the "Class"). O'Neill expressly disclaims any intent to seek any recovery in this action for personal injuries that O'Neill or any Class member may have suffered. Excluded from the New Jersey Subclass are Defendants; any

parent, subsidiary, or affiliate of Defendants; any entity in which any of the Defendants has or had a controlling interest, or which any of the Defendants otherwise controls or controlled; and any officer, director, employee, legal representative, predecessor, successor, or assign of any of Defendants.

98. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint.

99. **F.R.C.P. 23(a)(1) Numerosity**. The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, O'Neill reasonably estimates that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to O'Neill, the true number of Class members is known by Defendants. More specifically, Defendants maintain databases that contain the following information: (i) the name of each Class member who was prescribed the contaminated medication; (ii) the address of each Class member; and (iii) each Class member's payment information related to the contaminated medication. Thus, Class members may be identified and notified of the pendency of this action by U.S. Mail, electronic mail, and/or published notice, as is customarily done in consumer class actions.

100. **F.R.C.P. 23(a)(2) Existence and predominance of common questions of law and fact**. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

a. whether the Valsartan medications manufactured, distributed, and sold by Defendants were in fact contaminated with NDMA, thereby making the medication unfit for human consumption and therefore unfit for their intended purpose, and constituting a clear manufacturing defect for purposes of strict liability and negligence;

b. whether Defendants knew or should have known that the Valsartan medications were in fact contaminated with NDMA prior to the recall, thereby constituting fraud and/or fraudulent concealment, and negligence or gross negligence;

c. whether Defendants have unlawfully converted money from O'Neill and the Class;

d. whether Defendants are liable to O'Neill and the Class for fraudulent concealment;

e. whether Defendants are liable to O'Neill and the Class for violation of the Consumer Fraud Act, N.J.S.A. § 56:8-1 et seq.;

f. whether Defendants are liable to O'Neill and the Class for breaches of express and implied warranty;

g. whether O'Neill and the Class have sustained monetary loss and the proper measure of that loss;

h. whether O'Neill and the Class are entitled to declaratory and injunctive relief;

i. whether O'Neill and the Class are entitled to restitution and disgorgement from Defendants; and

j. whether the marketing, advertising, packaging, labeling, and other promotional materials for the Products are deceptive.

101. **F.R.C.P. 23(a)(3) Typicality**. O'Neill's claims are typical of the claims of the other members of the Class in that Defendants mass marketed and sold contaminated medications to consumers throughout the United States. This contamination was present in all of the

recalled medications manufactured, distributed, and sold by Defendants. O'Neill's claims are typical in that he was uniformly harmed in purchasing and consuming the contaminated medications. O'Neill's claims are further typical in that Defendants deceived O'Neill in the very same manner as they deceived each member of the Class. Further, there are no defenses available to Defendants that are unique to O'Neill.

102. **F.R.C.P. 23(a)(4) Adequacy of Representation**. O'Neill will fairly and adequately protect the interests of the Class. O'Neill has retained counsel that is highly experienced in complex consumer class action litigation, and O'Neill intends to vigorously prosecute this action on behalf of the Class. Furthermore, O'Neill has no interests that are antagonistic to those of the Class.

103. **F.R.C.P. 23(b)(3) Superiority**. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

104. In the alternative, the Class may also be certified because:

a. the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudication with respect to individual Class members that would establish incompatible standards of conduct for the Defendants;

b. the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

c. Defendants have acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

CAUSES OF ACTION

COUNT I: BREACH OF EXPRESS WARRANTY (N.J.S.A. § 12A:2-313)
(Individually and on Behalf of the Class)

105. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

106. Pursuant to N.J.S.A. § 12A:2-313, Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendants.

107. Each Defendant expressly warranted that its Valsartan product was fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with brand Diovan. In other words, Defendants expressly warranted that their products were the same as Diovan.

108. Each Defendant sold Valsartan product that they expressly warranted were compliant with cGMP and/or not adulterated.

109. Each Defendant's Valsartan product did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and/or was adulterated.

110. At the time that each Defendant marketed and sold its Valsartan product, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as brand Diovan, and cGMP compliant and/or not adulterated. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiff and other Class Members.

111. Each Defendant breached its express warranties with respect to its Valsartan product as it was not of merchantable quality, was not fit for its ordinary purpose, and did not comply with cGMP and/or was adulterated.

112. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

COUNT II: BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS (N.J.S.A. § 12A:2-314)
(Individually and on Behalf of the Class)

113. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

114. Pursuant to N.J.S.A. § 12A:2-314, Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

115. Each Defendant was a merchant within the meaning of the above statute.

116. Each Defendant's Valsartan product constituted "goods" or the equivalent within the meaning of the above statutes.

117. Each Defendant was obligated to provide Plaintiff and other Class Members reasonably fit Valsartan product for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

118. Each Defendant knew or should have known that its Valsartan product was being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to brand Diovan, and impliedly warranted that same was of merchantable quality and fit for that purpose.

119. Each Defendant breached its implied warranty because each Defendant's Valsartan product was not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

120. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

COUNT III: VIOLATION OF NEW JERSEY'S CONSUMER FRAUD ACT
(N.J.S.A. § 56:8-2)
(Individually and on Behalf of the Class)

121. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

122. Pursuant to N.J.S.A. § 56:8-1 *et seq*., Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

123. The Consumer Fraud Act, N.J.S.A. § 56:8-1 et seq., prohibits, inter alia:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise . . .
>
> N.J.S.A. § 56:8-2.

124. At all relevant times, Defendants were each a "person" within the meaning of N.J.S.A. § 56:8-1(d).

125. At all relevant times, Valsartan medications constituted "merchandise" within the meaning of N.J.S.A. § 56:8-1(c).

126. At all relevant times, Defendants' manufacturing, labeling, marketing, advertising, sales, and distribution of Valsartan medications met the definition of "advertisement" in N.J.S.A. § 56:8-1(a).

127. At all relevant times, Defendants' manufacturing, labeling, marketing, advertising, sales, and distribution of Valsartan medications met the definition of "sale" in N.J.S.A. § 56:8-1(e).

128. As described in detail above, Defendants falsely, deceptively, misleadingly, unfairly, and unconscionably represented to Plaintiff and the Class that the Valsartan medications were safe for consumption.

129. Defendants' above-described false, deceptive, misleading, unsubstantiated, and unconscionable claims that Valsartan medications are safe for consumption constitute affirmative misrepresentations and omissions in connection with the manufacture, marketing, advertising, promotion, distribution, and sale of Valsartan medications, in violation of the Consumer Fraud Act.

130. Defendants' false, deceptive, and misleading claims were material to Plaintiff's decision to purchase Valsartan medication, and they would have been material to any potential consumer's decision to purchase Valsartan medication. Similarly, the information about Valsartan medication that Defendants concealed from the public, including that no studies have been conducted on Valsartan medication, would have been material to Plaintiff or any other reasonable consumer's decision to purchase Valsartan medication.

131. Moreover, Defendants made such false, deceptive, and misleading statements, and concealed important information, about Valsartan medication with the intent that others rely on such statements and not become aware of the concealed information.

132. Therefore, Defendants have engaged in practices that are unconscionable, deceptive, and fraudulent and based on false pretenses, false promises, misrepresentations, and the knowing concealment, suppression, or omission of material fact with the intent that others rely on such concealment, suppression, or omission in their manufacturing, advertising, marketing, selling, and distribution of Valsartan medication. Defendants' labeling and advertising of Valsartan medication thus violates the Consumer Fraud Act.

133. Plaintiff and the other members of the Class purchased Valsartan medication for personal use and suffered damages in the form of ascertainable loss of money, including but not limited to the purchase price of Valsartan medication they paid, as a direct and proximate result of Defendants' labeling and advertising of Valsartan medication, which violates the Consumer Fraud Act. Plaintiff and the Class would not have purchased NDMA-containing medication if Defendants had not falsely, deceptive, misleadingly, and unconscionably claimed that Valsartan medications were safe for consumption.

134. By reason of the foregoing, Defendants are jointly and severally liable to Plaintiff and the other members of the Class for trebled compensatory damages, including but not limited to payment of a sum equal to treble the amount of a refund of all moneys acquired by reason of Defendants' marketing, advertising, promotion, distribution, or sale of Valsartan medication, plus reasonable attorneys' fees, filing fees, and reasonable costs of suit. N.J.S.A. §§ 56:8-2.11, 56:8-2.12, 56:8-19.

135. Defendants' conduct was intentional, wanton, willful, malicious, and in blatant disregard of, or grossly negligent and reckless with respect to, the life, health, safety, and well-being of Plaintiff and the other members of the Class, Defendants are therefore additionally liable for punitive damages, in an amount to be determined at trial.

136. Additionally, pursuant to N.J.S.A. § 56:8-19, Plaintiff and the Class make claims for damages, punitive damages, attorneys' fees, and costs.

COUNT IV: IN THE ALTERNATIVE, VIOLATION OF EACH STATE'S CONSUMER PROTECTION LAWS
(Individually and on Behalf of the Class)

137. Plaintiff hereby in by reference the allegations contained in all preceding paragraphs of this complaint.

138. Because of the acts and omissions alleged above, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of each state's consumer protection laws.

139. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

140. Each Plaintiff and other Class Member are consumers or persons aggrieved by Defendants' misconduct within the meaning of the above statutes.

141. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances.

142. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and other Class Members have suffered damages in an amount – an ascertainable loss – to be proved at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the Class, requests that the Court order the following relief and enter judgment against Defendants, jointly and severally, as follows:

A. An Order certifying the proposed Fed. R. Civ. P. 23(b)(3) Class and appointing Plaintiff and his counsel to represent the Class;

B. A judgment awarding Plaintiff and the Class damages in the amount of three times the loss of money that Plaintiff and the other members of the Class suffered, including but not limited to payment of a sum equal to treble the amount of a refund of all money acquired by reason of Defendants' marketing, advertising, promotion, distribution, or sale of Valsartan medication, the amount of such trebled loss to be determined at trial, plus reasonable attorneys' fees, filing fees;

C. A judgment awarding Plaintiff and the Class damages for Defendants' breach of express and implied warranties;

D. A judgment awarding Plaintiff and the Class restitution;

E. A judgment awarding Plaintiff and the Class punitive damages;

F. Prejudgment and postjudgment interest;

G. Attorneys' fees and expenses and the costs of this action; and

H. All other and further relief as the court deems necessary, just, and proper.

Dated: October 11, 2018

s/ Stefanie Colella-Walsh

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